Piramal Critical Care

K110608

JUL 20 2011

510(k) Summary or 510(k) Statement

510(k) Summary

Per 21 CFR 807.87(h), the following 510(k) summary is provided:

510(k) owner's name:	Piramal Critical Care, Inc.
Address:	50 Cobham Drive Orchard Park, NY 14127 Phone: (716) 855-1068 Fax: (716) 855-1078
Contact:	Jamie Keller Regulatory Compliance Specialist
Preparation Date:	March 2, 2011
Device Name:	Sevoflurane Vaporizer Adaptor
Common Name:	Vaporizer Filling Adaptor
Classification:	Anesthetic Vaporizer (21 CFR 868.5880, Product Code CAD)
Predicate Device:	Keyed Filler Bottle Adaptor (K053564)
Description of Device:	The Sevoflurane Vaporizer Adaptor will fit securely to the bottle and the vaporizer, ensuring minimal leakage. The adaptor is designed for use with QuikFil™ vaporizer filling technology and it is intended for multiple uses. The device complies with the requirements of ISO 5360:2006.
Intended Use:	The Sevoflurane Vaporizer Adaptor is intended to be used by qualified personnel as a means of filling Sevoflurane from a Piramal Sevoflurane bottle into a user-owned QuikFil™ Sevoflurane vaporizer.
Technological Characteristics:	The general design and materials of the Sevoflurane Vaporizer Adaptor is very similar to the predicate device. The only differences are the connection into the vaporizer and the model types. The Sevoflurane Vaporizer Adaptor connects to QuikFil™ vaporizers for filling sevoflurane anesthetic only. The predicate device connects to Key-Fill vaporizers only and has four model types for filling halothane, enflurane, isoflurane and sevoflurane anesthetics. These differences do not make the Sevoflurane Vaporizer Adaptor any less safe or less effective than the predicate device.

This concludes the 510(k) summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Jamie Keller
Regulatory Compliance Specialist
Piramal Critical Care, Incorporated
50 Cobham Drive
Orchard Park, New York 14127

JUL 20 2011

Re: K110608
Trade/Device Name: Sevoflurane Vaporizer Adaptor
Regulation Number: 21 CFR 868.5880
Regulation Name: Anesthetic Vaporizer
Regulatory Class: II
Product Code: CAD
Dated: July 8, 2011
Received: July 11, 2011

Dear Ms. Keller:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28,1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known):

K110608

Device Name:

Sevoflurane Vaporizer Adaptor

Indications For Use:

The Sevoflurane Vaporizer Adaptor is intended to be used by qualified personnel as a means of filling Sevoflurane from a Piramal Sevoflurane bottle into a user-owned QuikFil™ Sevoflurane vaporizer.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(K) Number: K110608

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)